K091196

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	April 8, 2009
Trade Name:	GRS™ Glenoid Resurfacing System
Common Name:	Shoulder joint prosthesis, glenoid component
Device:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Regulation:	Regulation Number 888.3660
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KWS

OCT 2 7 2009

Device Indications for Use

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Device Description

The Arthrosurface® glenoid components are intended to interface and articulate with the Sponsor's previously cleared and commercially marketed humeral head resurfacing prosthesis (K023096) to repair and replace a shoulder joint when both articular surfaces of the joint are affected. They are comprised of Ultra High Molecular Weight Polyethylene (UHMWPE) and are offered in both a peg and

K091196

keel design. These components will be available in several sizes and are intended to be implanted using bone cement.

Substantial Equivalency:

The intended use, materials, and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

• DePuy Global™ Shoulder Glenoid Component	K981487
• Biomet Modular Hybrid Glenoid	K060694
• Synthes Epoca Shoulder Prosthesis System	K072578

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Arthrosurface, Inc.
% Ms. Dawn Wilson
28 Forge Parkway
Franklin, Massachusetts 02038

OCT 2 7 2009

Re: K091196
Trade/Device Name: GRS™ Glenoid Resurfacing System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: October 20, 2009
Received: October 22, 2009

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091196

Section 4 - Indications for Use Statement

510(k) Number (if known): K091196

Device Name: GRS™ Glenoid Resurfacing System

Indications for Use:

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Prescription Use __√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marietta J. for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091196